



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

28/MAR/2017

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for Sharda Fluroxypyr MHE  
Technical

Subject: Name of Pesticide Product: Sharda Fluroxypyr MHE Technical  
EPA File Symbol: 82633-EO  
DP Barcode: D435499  
Decision No.: 519447  
Action Code: R334  
PC Code: 128968 (fluroxypyr 1-methylheptyl ester)

From: Eugenia McAndrew, Biologist  
Chemistry, Inerts and Toxicology Assessment Branch  
Registration Division (7505P)

Through: John C. Redden, M.S., Senior Risk Assessor  
Chemistry, Inerts and Toxicology Assessment Branch  
Registration Division (7505P)

To: Karen Samek, RM Team 23  
Herbicide Branch  
Registration Division (7505P)

Applicant: Sharda Cropchem Ltd.  
7217 Lancaster Pike, Suite A  
P.O. Box 640  
Hockessin, DE 19707

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fluroxypyr 1-methylheptyl ester	99.21
<u>Other Ingredient(s):</u>	<u>0.79</u>
Total: 100.00%	

**ACTION REQUESTED:** The Risk Manager requests a review of acute toxicity studies submitted in support of Sharda Fluroxypyr MHE Technical, EPA File Symbol 82633-EO.

**BACKGROUND:** Sharda Cropchem Ltd. has submitted six acute toxicity studies (MRIDs 499623-04 to -09) to support the registration of Sharda Fluroxypyr MHE Technical, EPA File Symbol 82633-EO. The submission also includes a label, company letter and basic CSF dated July 8, 2016 which must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

**GLP:** All studies were conducted in accordance with GLP.

**DEFICIENCIES:** None

**LABEL:** The following are the precautionary and first aid statements for this product, as obtained from the Label Review System:

**PRODUCT ID #:** 82633-EO

**PRODUCT NAME:** Sharda Fluroxypyr MHE Technical

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

### DATA EVALUATION RECORD

**Product Reg. No.:** 82633-EO

**Product Name:** Sharda Fluroxypyr MHE Technical

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 82633-EO:

<b>1. DP BARCODE:</b> 435499				
<b>2. PC CODE:</b> 128968				
<b>3. CURRENT DATE:</b> March 28, 2017				
<b>4. TEST MATERIAL:</b> Fluroxypyr-meptyl TC: (Batch #: JLFM70201; Purity: 98.2%; pH 5.9; white powder)				
<b>Study/Species/Lab Study # /Date</b>	<b>MRID</b>	<b>Results</b>	<b>Tox Cat</b>	<b>Core Grade</b>
Acute oral toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0009/April 2, 2009 OCSPP 870.1100; OECD 420	49962304	LD <sub>50</sub> Females > 2000 mg/kg bw  The test item was prepared as a suspension in arachis oil BP. (Test material did not dissolve or suspend in distilled water.)  One female was tested at a limit dose of 2000 mg/kg in a sighting study. Four additional females were dosed at 2000 mg/kg.  All animals survived and gained weight. No clinical signs of toxicity were noted. No gross abnormalities were observed at necropsy.	III	A
Acute dermal toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0010/April 21, 2009 OCSPP 870.1200; OECD 402	49962305	LD <sub>50</sub> > 2000 mg/kg bw (both sexes)  The test item was moistened with arachis oil BP prior to application.	III	A

		All rats survived. One female did not gain weight during the first week but all animals gained weight by study termination. No clinical signs of toxicity or dermal irritation were observed. No abnormalities were observed at necropsy.		
Acute inhalation toxicity / rat Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0014/May 5, 2009 OCSPP 870.1300; OECD 403	49962306	<p>LC<sub>50</sub> &gt; 6.11 mg/L (both sexes)</p> <p>MMAD 3.69 GSD: 3.14</p> <p>All animals survived. Two females lost weight during the study and one female did not gain weight. All other animals showed bodyweight gains. During exposure, increased respiratory rate and wet fur was noted for all animals. On removal from the chamber, all animals showed increased respiratory rate, wet fur, hunched posture and piloerection. The animals appeared normal by day 1. Red brown staining of the fur around the neck of one female was noted on day 1 only. At necropsy, abnormally dark lungs were noted in one female. No other abnormalities were observed.</p>	IV	A
Primary eye irritation / rabbit Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0011/April 14, 2009 OCSPP 870.2400; OECD 405	49962307	<p>3 males tested pH = 9.1 as a 10% aqueous preparation of the test material</p> <p>A volume of 0.1 mL (approx. 94 mg) of test material was instilled into each eye.</p>	IV	A

		No corneal opacity or iritis were observed. Positive conjunctival redness was observed in all eyes at one hour decreasing to a score of 1 at 24 hours. Scores of 1 were noted for chemosis and discharge at 1 and 24 hours. All eyes were free of irritation by 48 hours.										
Primary dermal irritation / rabbit Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0012/April 14, 2009 OCSPP 870.2500; OECD 404	49962308	3 males tested  PDI = 0.0 (non-irritating)  pH 9.1 (as a 10% w/w aqueous preparation)  A quantity of 0.5 g of the test item was moistened sufficiently with 0.5 mL of distilled water and applied to the skin of each rabbit.  No dermal irritation was observed at any of the test sites.	IV	A								
Dermal sensitization /mouse Harlan Laboratories Ltd Derbyshire, UK Project # 2715/0013/March 30, 2009 OCSPP 870.2600; OECD 429	49962309	This product is <u>not</u> a dermal sensitizer.  <table><thead><tr><th><u>% tested</u></th><th><u>Stimulation Index*</u></th></tr></thead><tbody><tr><td>5</td><td>1.19</td></tr><tr><td>10</td><td>0.94</td></tr><tr><td>25</td><td>1.28</td></tr></tbody></table> *Stimulation Index values < 3 are negative results.  Appropriate historical positive control study is provided.	<u>% tested</u>	<u>Stimulation Index*</u>	5	1.19	10	0.94	25	1.28	-	A
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**Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap  
W = Waived**